



## Santa Clara Law Review

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Volume 54 | Number 3

Article 5

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8-21-2014

# Antitrust Liability for Maintaining Baseless Litigation

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## ANTITRUST LIABILITY FOR MAINTAINING BASELESS LITIGATION

**Saami Zain\***

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### INTRODUCTION

Courts and legal scholars regularly debate and criticize the deleterious effects of frivolous litigation. These lawsuits needless tax litigants, wastefully drain judicial resources, and potentially stymie society and the economy as a whole.<sup>1</sup> As a result, ethical, procedural

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1. For a summary of common criticisms pertaining to frivolous litigation, *see, e.g.*, John Lande, *Failing Faith in Litigation? A Survey of Business Lawyers’ and Executives’*

and substantive rules have been crafted to attempt to deter these ill-favored actions.<sup>2</sup> However, many fail to consider that frivolous litigation may also be employed as a tactic to hinder competition.

Frivolous litigation may have detrimental effects beyond the litigants involved and courts. In certain situations, such litigation may harm competition by adversely effecting conduct of other (non-litigating) market participants, such as suppliers, distributors, purchasers, and even consumers. Consequently, it has long been held that objectively baseless—or “sham”—litigation that is done to impede competition and which has that effect may violate the antitrust laws.<sup>3</sup> Nonetheless, many scholars and courts continue to underrate or even overlook the injury caused by anticompetitive sham litigation. This article uses the nomenclature “antitrust sham litigation” to refer to antitrust claims (or counterclaims) predicated on sham litigation.

Antitrust challenges to sham litigation arise in various contexts involving a variety of factual and legal claims. However, one commonality is that many such cases appear to focus exclusively on the time the case was initially filed.<sup>4</sup> That is, the crux of the claim is that *at the time filed*, the lawsuit was baseless and filed for an improper purpose.<sup>5</sup> Indeed, the author is not aware of any reported, successfully litigated case where an antitrust claim was based on a party *maintaining* a baseless lawsuit.<sup>6</sup> As modern litigation is often lengthy, complex, and resource intensive, it is not improbable that, regardless of the merits of the action when filed, at some point in the litigation process, it may become manifestly evident that no reasonable litigant could expect success on the merits. And at that point, maintaining the action is likely to be objectively baseless and unjustifiable.

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*Opinions*, 3 HARV. NEGOT. L. REV. 1, 26 (1998); Valerie P. Hans & William S. Lofquist, *Jurors' Judgments of Business Liability in Tort Cases: Implications for the Litigation Explosion Debate*, 26 LAW & SOC'Y REV. 85, 95 (1992); John W. Wade, *On Frivolous Litigation: A Study of Tort Liability and Procedural Sanctions*, 14 HOFSTRA L.REV. 433, 433 (1986).

2. See *infra* Parts II and III.

3. See, e.g., *Prof'l Real Estate Investors, Inc. v. Columbia Pictures, Inc.*, 508 U.S. 49, 62 (1993); *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 511 (1972); *Primetime 24 Joint Venture v. Nat'l Broadcasting Corp., Inc.*, 219 F.3d 92, 100–01 (2d Cir. 2000).

4. See, e.g., *Handgards Inc. v. Ethicon Inc.*, 743 F.2d 1282, 1288–89 (9th Cir. 1984); *Nabi Biopharmaceuticals v. Roxane Labs*, No. 2:05-CV-889, 2007 WL 894473, at \*2 (S.D. Ohio Mar. 21, 2007).

5. See *id.*

6. While the author is aware of cases where both the filing and maintaining the action was alleged to be a sham, those opinions focus primarily on the filing of the suit (possibly because if it is found that the litigation was a sham when filed, maintaining it was certainly so as well). See *id.*

Continuing to litigate a baseless lawsuit with the purpose and effect of impeding competition may violate the antitrust laws. As an example, in the context of pharmaceuticals, branded drug manufacturers often sue generic drug manufactures for patent infringement. In many of these cases, an antitrust claim is made against the branded drug manufacturer, alleging that the infringement litigation was objectively baseless and made solely for the purpose of delaying generic competition. And while antitrust challenges to sham litigation are not limited to the pharmaceutical context, for several reasons these cases are particularly useful in revealing potential anticompetitive effects of sham litigation. First, the rising costs of prescription drugs has long been an issue of national concern.<sup>7</sup> And because generic drugs are usually substantially cheaper than their branded counterparts, encouraging vigorous generic competition offers a means of reducing these costs. Second, the focus of the dispute, *i.e.* whether a generic drug infringes upon a branded drug's patents, suggests that in certain situations the inquiry need not be extensive. For instance, a cursory comparison of the generic's product (or method) to the patented formulation (or method) may be all that is necessary to demonstrate non-infringement.<sup>8</sup> Third, because of certain intrinsic features of its regulatory framework, pharmaceuticals is an area where proving anticompetitive effects of sham litigation may be relatively easy (*i.e.*, compared to in other contexts).<sup>9</sup> Indeed, the pharmaceutical industry has long been criticized as an industry in which companies have been able to successfully manipulate the regulatory process with anticompetitive results.<sup>10</sup> Part II provides a

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7. *E.g.*, Elizabeth Rosenthal, *The Soaring Price of a Simple Breath*, N.Y. Times, Oct. 13, 2013 at A1 (finding that drug costs are 10% of the country's \$2.7 trillion annual health bill). According to the U.S. Department of Health and Human Services, Center for Medicare & Medicaid Service, retail prescription drug spending in 2012 was about \$263.3 billion. See *National Health Expenditure 2012 Highlights*, CTR. FOR MEDICARE & MEDICAID SERVS., (Jan. 9, 2013, 8:34 AM), <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf>.

8. See, *e.g.*, *AstraZeneca AB v. Dr. Reddy's Laboratories, Ltd.*, No. 07 Civ. 6790(CM), 2010 WL 1375176, at \*4-5 (S.D.N.Y. Mar. 30, 2010). Concededly, infringement analysis is often not a simple task.

9. See *infra* Part IIB, discussing how the mere filing of litigation by a branded drug manufacturer may delay approval of a generic version of the drug—and thus the cost reductions associated with generic competition—for at least 30 months.

10. See, *e.g.*, *Caraco Pharm. Laboratories v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012) ("In the late 1990's, evidence mounted that some brands were exploiting this [Hatch-Waxman] statutory scheme to prevent or delay the marketing of generic drugs . . ."); JEREMY BULOW, *The Gaming of Pharmaceutical Patents*, in 4 INNOVATION POLICY AND

basic overview of applicable legal principles, i.e., antitrust, patents, pharmaceuticals, and laws governing frivolous litigation.<sup>11</sup> Part III discusses pharmaceutical cases where the litigation is alleged to be a sham due to non-infringement (rather than because of patent invalidity, fraud or inequitable conduct).<sup>12</sup> Part IV provides an analysis and makes the case for antitrust liability for maintaining baseless litigation in appropriate circumstances.<sup>13</sup> Finally, Part V offers a short conclusion.<sup>14</sup>

## II. BACKGROUND OF APPLICABLE LEGAL PRINCIPLES

The following provides a short background on the applicable laws and legal principles. In addition to antitrust and patents, a brief summary of laws governing pharmaceuticals and frivolous litigation is provided.

### A. Antitrust Law & Sham Litigation

The antitrust laws are intended to protect competition and consumers.<sup>15</sup> The Sherman Act is the cornerstone of these laws and has been evaluating whether conduct is anticompetitive for well over a hundred years.<sup>16</sup> It proscribes both joint conduct among firms that “unreasonably” harms competition<sup>17</sup> as well as “monopolization.”<sup>18</sup> In

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THE ECONOMY 145 (Adam B. Jaffe et al. eds. 2004); Elizabeth Powell-Bullock, *Gaming the Hatch-Waxman System: How Pioneer Drug Makers Exploit the Law to Maintain Monopoly Power in the Prescription Drug Market*, 29 J. LEGIS. 21, 21 (2002); *Generic Entry Prior to Patent Expiration: An FTC Study*, FED. TRADE COMM’N, <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> (July, 2002).

11. See *infra* Part II.

12. See *infra* Part III.

13. See *infra* Part IV.

14. See *infra* Part V.

15. *United States v. Topco Associates, Inc.*, 405 U.S. 596, 610 (1972) (“Antitrust laws in general, and the Sherman Act in particular, are the Magna Carta of free enterprise. They are as important to the preservation of economic freedom and our free-enterprise system as the Bill of Rights is to the protection of our fundamental personal freedoms.”). Consumer welfare is the primary focus of the antitrust laws. See, e.g., *United States v. Microsoft Corp.*, 253 F.3d 34, 58 (D.C. Cir. 2001); *Spanish Broad. Sys. of Fla. v. Clear Channel Commc’ns, Inc.*, 376 F.3d 1065, 1072 (11th Cir. 2004); *K.M.B. Warehouse Distribs. v. Walker Manufacturing*, 61 F.3d 123, 128 (2nd Cir. 1995). See also Philip Areeda & Herbert Hovenkamp, *FUNDAMENTALS OF ANTITRUST LAW* § 6.04d (3rd ed. 2004).

16. Sherman Act of 1890, ch. 647, 26 Stat. 209 (codified as amended at 15 U.S.C. §§ 1–7 (2012)).

17. 15 U.S.C. § 1 (2012). Section 1 of the Sherman Act prohibits certain joint conduct that harms competition, providing in part: “[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.” *Id.* Despite its broad, prohibitive terms, it has long been held that Section 1 only condemns “unreasonable” restraints. *Standard Oil*

examining whether conduct is “unreasonable” for antitrust purposes, courts typically determine whether the challenged conduct is, on the whole, anticompetitive, by evaluating and balancing all anticompetitive effects against pro-competitive justifications.<sup>19</sup> This inquiry, termed the “rule of reason” in antitrust parlance, is both flexible and fact specific, and usually requires an assessment of the relevant industry, the firms involved in the litigation, the nature of the conduct being challenged as unlawful, all asserted pro-competitive business justifications for the conduct, and the actual and likely effects of the conduct.<sup>20</sup>

Monopolization may be described as exclusionary conduct, i.e., conduct other than competition on the merits and done for the purpose of obtaining or maintaining monopoly power.<sup>21</sup> It has two elements: “(1) the possession of monopoly power in the relevant market and (2)

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Co. of N.J. v. United States, 221 U.S. 1, 2 (1910).

18. 15 U.S.C. § 2. Section 2 of the Sherman Act provides in part: “[e]very person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony . . . .” *Id.*

19. *See, e.g.*, Bd. of Trade of the City of Chi. v. United States, 246 U.S. 231, 238 (1918). Specifically, the Supreme Court of the United States stated:

[t]he true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition. To determine that question the court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable. The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts.

*Id.*

20. *See* WILLIAM C. HOLMES & MELISSA H. MANGIARACINA, ANTITRUST LAW HANDBOOK 160 (2012-2013 ed.). Because this analysis is extensive and often resource-intensive, courts have identified circumstances when it may be truncated or even obviated. For example, it has long been held that certain types of conduct are so likely to have substantial anticompetitive effects and to have no significant procompetitive benefits that such conduct may be condemned outright and held to be *per se* illegal, i.e., without any assessment of its particular effects. *See, e.g.*, N. Pac. Ry. Co. v. United States, 356 U.S. 1, 5 (1958) (“[T]here are certain agreements or practices which, because of their pernicious effect on competition and lack of any redeeming virtue, are conclusively presumed to be unreasonable, and therefore illegal, without any elaborate inquiry as to the precise harm they have caused or the business excuse for their use.”). Alternatively, conduct that is not deemed *per se* illegal, but nevertheless “appears likely, absent an efficiency justification, to restrict competition and decrease output,” may be presumed to be “unreasonable” without an extensive analysis— although the presumption is rebuttable upon plausible and legally cognizable pro-competitive justification(s). *See, e.g.*, Polygram Holding Inc. v. FTC, 416 F.3d 29, 32–33 (D.C. Cir. 2005) (internal quotation marks omitted). This type of analysis is sometimes referred to as a “quick look” analysis. *See, e.g.*, Cal. Dental Ass’n v. FTC, 526 U.S. 756, 763 (1999).

21. *E.g.*, United States v. Grinnell Corp., 384 U.S. 563, 570–71 (1966).

the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.”<sup>22</sup> Civil remedies for an antitrust violation may include an injunction,<sup>23</sup> restitution,<sup>24</sup> disgorgement,<sup>25</sup> and treble damages.<sup>26</sup>

Filing frivolous lawsuits has the potential to be anticompetitive regardless of whether done to protect a firm’s market power or as a joint strategy among firms to impede competition. Litigation is often costly, and thus if meritless, may thwart or undermine competition.<sup>27</sup> For example, baseless litigation filed by a dominant firm against a competitor may deter suppliers and/or purchasers from dealing with the competitor due to anxiety over provoking litigation or disfavored treatment by the dominant firm. And even a company without any apprehension about retaliation from the dominant firm may nonetheless decline to do business with the competitor so as to avoid any legal uncertainties (such as may be the case when the competitor’s product is alleged to be infringing a patent).

Although antitrust is primarily concerned with the protection of competition, it recognizes that in certain, limited circumstances, competition concerns may have to defer to other policy goals.<sup>28</sup> As a result, certain conduct has been granted immunity from antitrust liability, regardless of the extent of anticompetitive effects.<sup>29</sup> For example, two of the most commonly known of these immunities are the statutory exemption relating to certain acts by organized labor,<sup>30</sup> and the exemption applying to professional baseball.<sup>31</sup> More relevant is the

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22. *Id.*

23. 15 U.S.C. § 26.

24. *See, e.g.,* *United States v. Paramount Pictures*, 334 U.S. 131, 171–72 (1948).

25. *See id.*

26. 15 U.S.C. § 15(a).

27. So long as the baseless litigation impedes or even interferes with the competitive process, there is an argument that it may be anticompetitive, regardless of whether it results in any measure anticompetitive effects.

28. *See, e.g.,* *United States v. Hutcheson*, 312 U.S. 219, 229–31.

29. *See id.*

30. *See* Norris-La Guardia Act of 1932, ch. 90, 47 Stat. 70–73 (codified as amended at 29 U.S.C. §§ 101–110) (2012). The purpose of the statute was discussed by the Supreme Court in *Hutcheson*:

The Norris-La Guardia Act reasserted the original purpose of the Clayton Act by infusing into it the immunized trade union activities as redefined by the later Act.

In this light [section] 20 removes all such allowable conduct from the taint of being a ‘violation of any law of the United States’, including the Sherman Law.

*Hutcheson*, 312 U.S. at 236.

31. *See* *Toolson v. N.Y. Yankees, Inc.*, 346 U.S. 356, 357 (1953) (“Congress had no intention of including the business of baseball within the scope of the federal antitrust laws.”); *Flood v. Kuhn*, 407 U.S. 258, 284 (1972) (upholding the *Toolson* decision).

*Noerr-Pennington* doctrine, which is based on constitutional principles supporting the right to petition the government, and provides that “[t]hose who petition government for redress are generally immune from antitrust liability.”<sup>32</sup> Courts have interpreted *Noerr-Pennington* immunity to include the filing of litigation for the purpose of vindicating legal rights.<sup>33</sup> *Noerr-Pennington* immunity thus subordinates antitrust’s concerns that litigation may be used as an anticompetitive weapon,<sup>34</sup> in favor of broadly permitting the enforcement of legal rights via litigation.

Antitrust immunity granted by *Noerr-Pennington* is not without limits, however. Rather, antitrust attempts to deal with the tension caused by allowing bona fide litigation and yet still curbing abusing, anticompetitive lawsuits by denying any immunity to frivolous litigation. Accordingly, antitrust immunity is not granted to litigation that is a mere “sham,” i.e., “encompass[ing] situations in which [a] person use[s] the government process—as opposed to the outcome of that process—as an anticompetitive weapon.”<sup>35</sup> Litigation that is both objectively baseless “in the sense that no reasonable litigant could realistically expect success on the merits,” and is subjectively improper, i.e., “conceals ‘an attempt to interfere directly with the business relationships of a competitor,’” is thus not afforded antitrust

32. *Prof'l Real Estate Investors, Inc. v. Columbia Pictures, Inc.*, 508 U.S. 49, 56 (1993). The so-called *Noerr-Pennington* doctrine is the result of two Supreme Court cases: *E. R.R. President's Conference v. Noerr Motor Freight*, 365 U.S. 127 (1965) and *United Mine workers of America v. Pennington*, 381 U.S. 657 (1965). In *Noerr*, the Court held that concerted efforts to seek legislative relief were immune from antitrust liability, even though they may be anticompetitive. *Noerr*, 365 U.S. at 136. In *Pennington*, concerted petitioning efforts by mineworkers and mines seeking higher minimum wages for companies selling coal to a federal agency were held to be immune. *Pennington*, 381 U.S. at 661.

33. See, e.g., *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510–11 (1972) (holding that the *Noerr-Pennington* doctrine did not apply where defendants had sought to intervene in licensing proceedings for competitors because the intervention was done to harass competitors).

34. An example of an area where much concern has been raised about potentially anticompetitive litigation is litigation by “patent trolls,” entities that acquire patents for the sole purpose of monetizing them via litigation or licensing rather than using them to innovate. See, e.g., Colleen V. Chien, *Of Trolls, Davids, Goliaths, and Kings: Narratives and Evidence in the Litigation of High-Tech Patents*, 87 N.C. L. REV. 1571, 1573–74 (2009); Robin M. Davis, *Failed Attempts to Dwarf the Patent Trolls: Permanent Injunctions in Patent Infringement Cases Under the Proposed Patent Reform Act of 2005 and Ebay v. Mercexchange*, 17 CORNELL J.L. & PUB. POL'Y 431, 431–32 (2008); J.P. Mello, *Technology Licensing and Patent Trolls*, 12 B.U. J. SCI. & TECH. L. 388, 388 (2006); Joe Beyers, *Perspective: Rise of the Patent Trolls*, CNET NEWS (Oct. 12, 2005), [http://news.cnet.com/rise+of+the+patent+trolls/2010-1071\\_3-5892996.html](http://news.cnet.com/rise+of+the+patent+trolls/2010-1071_3-5892996.html).

35. *City of Columbia v. Omni Outdoor Adver.*, 499 U.S. 365, 380 (1991).



immunity.<sup>36</sup> However, proving that litigation is a “sham” under *Noerr-Pennington* merely strips a litigant of antitrust immunity; it does not impose liability by itself.<sup>37</sup> Rather, “even a plaintiff who defeats the defendant’s claim to *Noerr* immunity by demonstrating both the objective and subjective components of a sham must still prove a substantive antitrust violation.”<sup>38</sup>

### B. The Hatch-Waxman Act

The high and rising cost of health care in the United States is an issue of national importance and concern. It is estimated that in 2010, total health care expenditures accounted for nearly eighteen percent of gross domestic product.<sup>39</sup> And pharmaceuticals continue to be a significant portion of that cost, estimated at over \$263 billion in 2012.<sup>40</sup>

In the United States, the sale of pharmaceuticals is heavily regulated. The Federal Food, Drug, and Cosmetics Act (“Act”) and its implementing regulations govern, *inter alia*, the manufacturing, sale and marketing of pharmaceuticals in the United States.<sup>41</sup> Under the Act, anyone seeking to bring a new drug to market must submit a New Drug Application (“NDA”) with the Food and Drug Administration (“FDA”) and provide scientific data demonstrating that the drug is safe and effective for its intended use.<sup>42</sup> A company filing an NDA must also provide FDA with information on all composition or method patents that it claims covers the drug for which it seeks approval and “with respect to which a claim of patent infringement could reasonably

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36. *Prof'l Real Estate Investors* 508 U.S. at 60–61 (quoting *Noerr*, 365 U.S. at 144). A similar type of antitrust claim is enforcement of a fraudulent procured patent. *See, e.g., Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 174 (1965) (“The enforcement of a patent procured by fraud on the Patent Office may be violative of §2 of the Sherman Act provided the other elements necessary to a §2 case are present.”). Sham litigation and *Walker-Process* claims are similar, but distinct legal theories. *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1071 (Fed. Cir. 1998) (“*PRE* and *Walker Process* provide alternative legal grounds on which a patentee may be stripped of its immunity from the antitrust laws; both legal theories may be applied to the same conduct.”).

37. *Prof'l Real Estate Investors*, 508 U.S. at 61.

38. *Id.*

39. THE HENRY J. KAISER FAMILY FOUND., HEALTH CARE COSTS: A PRIMER 1 (May 2012), available at <http://kaiserfamilyfoundation.files.wordpress.com/2013/01/7670-03.pdf>

40. *See National Health Expenditure 2012 Highlights*, CTR. FOR MEDICARE & MEDICAID SERVS., <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf>.

41. *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 351–360eee4 (2012).

42. 21 U.S.C. § 355(b)(1); *See also* *Caraco Pharm. Laboratories v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012).

be asserted.”<sup>43</sup> FDA may approve an NDA for one or multiple uses.<sup>44</sup> Once an NDA is approved, FDA lists the drug, along with information about the applicable patents, in its publication “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly referred to as the “Orange Book.”<sup>45</sup>

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act,<sup>46</sup> commonly referred to as the Hatch-Waxman Act, amending the Act to encourage generic entry by permitting a quicker, easier means for generic drugs to come to market.<sup>47</sup> Under the Hatch-Waxman Act, companies seeking to market generic versions of a drug that has already been approved pursuant to an NDA may obtain FDA approval by filing an Abbreviated New Drug Application (ANDA), and demonstrating that their generic version is “bioequivalent” to the drug approved under the NDA.<sup>48</sup> Approval of an ANDA is limited to the same uses approved for the NDA, and is contingent upon compliance with additional substantive and procedural requirements, including having to evaluate whether its proposed generic would infringe upon any patent(s) listed in the Orange Book as covering the NDA.<sup>49</sup> Specifically, the ANDA filer must certify one of the following: (I) no patent information is listed in the Orange Book for the drug approved by the NDA; (II) the listed patent(s) have expired; (III) the listed patents will expire before the generic product is marketed; or (IV) the patents listed are invalid or will not be infringed by the generic.<sup>50</sup> When a generic company challenges a patent’s validity or asserts non-infringement—referred to as a “paragraph IV

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43. 21 U.S.C. § 355(b)(1)(G).

44. *Caraco*, 132 S. Ct. at 1676.

45. *Id.* See also U.S. FOOD & DRUG ADMIN., ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (Feb. 2014), available at <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>.

46. Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 21 U.S.C. § 301 (1984)).

47. *E.g., In re K-Dur Antitrust Litig.*, 686 F.3d 197, 204 (3d Cir. 2012) (“Congress explained that the purpose of the Hatch-Waxman Act is ‘to make available more low cost generic drugs.’”) (citation omitted); *Kaiser Found. Health Plan, Inc. v. Abbott Labs., Inc.*, 552 F.3d 1033, 1036 (9th Cir. 2009) (“The Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the ‘Hatch-Waxman Act’ or ‘Hatch-Waxman,’ was passed to facilitate the approval of generic versions of brand-name drugs.”).

48. 21 U.S.C. § 355(j)(2)(A). A generic is “bioequivalent” to a branded drug when “the rate and extent of absorption of the generic drug is not significantly different from the rate and extent of absorption of the branded drug, when administered at the same dosage. *Id.* § 355(i)(8)(B).

49. *Id.* § 355(j)(2)(A)(vii); see also *Caraco*, 132 S. Ct. at 1676 (“Because the FDA cannot authorize a generic drug that would infringe a patent, the timing of an ANDA’s approval depends on the scope and duration of the patents covering the brand-name drug.”).

50. 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV).

certification”—it must also set forth “a detailed statement of the factual and legal basis for the applicant’s opinion that the patent is not valid or will not be infringed.”<sup>51</sup> A limited exception to this requirement is when the ANDA seeks approval for a drug use that is not covered by any patent listed in the Orange Book.<sup>52</sup> Under those circumstances, the generic may instead provide a statement asserting that its ANDA does not seek approval for any use claimed by any Orange Book patent (i.e., it seeks to market the drugs only for approved but unpatented uses).<sup>53</sup>

The Hatch-Waxman Act creates a unique method for branded and generic drug manufacturers to resolve patent issue. Rather than requiring a generic drug manufacturer to first create and distribute a potentially infringing product (the usual prerequisite to infringement litigation), the Act allows patent litigation to go forward prior to the sale and even FDA approval of a generic product.<sup>54</sup> Thus, the Act provides that the mere filing of a paragraph IV certification is an “artificial act of infringement,” permitting the holder of the NDA to file an infringement action against the generic manufacturer—even though no infringing product is on the market (as FDA has not yet approved the ANDA).<sup>55</sup> Thereafter, if the NDA holder initiates patent litigation

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51. *Id.* § 355(b)(3)(D)(ii).

52. *See Caraco*, 132 S. Ct. at 1681–82. *See also* *Warner Lambert v. Apotex*, 316 F.3d 1348, 1362, 1365 (Fed. Cir. 2003); *Bayer Schering Pharma v. Lupin*, 676 F.3d 1316 (Fed. Cir. 2012)(no infringement when a generic drug manufacturer’s ANDA only seeks FDA approval to market its drug for unpatented uses)..

53. 21 U.S.C. § 355(j)(2)(A)(viii). In such cases, the generic must submit a proposed label that “carves out” the NDA’s method patent. *E.g.*, *Caraco*, 132 S. Ct. at 1682; *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1318–19 (Fed. Cir. 2012); *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1374 (Fed. Cir. 2012) (“Where the Orange Book lists a method of use patent that ‘does not claim a use for which the applicant is seeking approval,’ an applicant may instead submit a statement under 21 U.S.C. § 355(j)(2)(A)(viii) averring that the ANDA excludes all uses claimed in the patent.”) (citation omitted). Thus, “a patented method of using a drug can only be infringed under [section] 271(e)(2) by filing an ANDA that seeks approval to market the drug for that use.” *AstraZeneca*, 669 F.3d at 1379 (citing *Warner–Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358–59 (Fed. Cir. 2003)). Thus, an ANDA seeking to market a drug not covered by a composition patent for unpatented methods of treatment cannot infringe under section 271(e)(2). *Id.* at 1354–55 (“[W]e conclude that it is not an act of infringement to submit an ANDA for approval to market a drug for a use when neither the drug nor that use is covered by an existing patent, and the patent at issue is for a use not approved under the NDA.”).

54. *See* 21 U.S.C. § 355(c)(3)(D).

55. *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). *See also In re Wellbutrin XL Antitrust Litig.*, Nos. 08–2431 (direct), 08–2433 (indirect), 2012 WL 1657734, at \*9 (E.D. Pa. May 11, 2012) (“An infringement inquiry triggered by an ANDA filing is focused on the product that is likely to be sold following FDA approval. Because the potentially infringing drug has not yet been marketed when the patent holder files suit, the inquiry is a hypothetical one that asks the fact finder to determine whether the drug that will be sold upon approval of the ANDA will infringe the asserted patent.”) (citing *Bayer AG*, 212 F.3d at 1248–49).

against a company which submitted a paragraph IV certification, FDA approval of that generic company's ANDA is automatically delayed for thirty months or until the patent is held to be invalid or not infringed.<sup>56</sup> In contrast, if the NDA holder does not file suit within 45 days, FDA may approve the ANDA immediately, provided that all other conditions for approval have been met, i.e., the drug is deemed safe and efficacious.<sup>57</sup> By this means, the Act creates a way for the generic and branded drug manufacturers to work out patent disputes prior to the generic incurring the cost of entry and production (as well as avoiding damages for infringement).

### *C. Patent Law*

Whoever invents a useful, novel, and non-obvious process, machine, manufacture, or composition of matter may obtain a patent on that invention.<sup>58</sup> A patent grants its holder (the "patentee") the "right to exclude others from making, using, offering for sale, or selling the invention."<sup>59</sup> One who makes, uses or sells a product covered by a patent without a patentee's authorization is said to have infringed the patent.<sup>60</sup>

Patents are issued by the United States Patent & Trademark Office.<sup>61</sup> A patent document contains various sections.<sup>62</sup> Of particularly importance is the patents' "specification" and its "claims."<sup>63</sup> The specification contains a "written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains" to make or use the invention.<sup>64</sup> Each patent has at least one claim, in which the inventor must "explicitly identify[y] the subject matter of the invention and particularly poin[t] out and distinctly clai[m] the subject matter" of the invention.<sup>65</sup> "The

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56. *Eli Lilly*, 496 U.S. at 677–78.

57. *Id.* at 677; 21 U.S.C. § 355(c)(3)(C). *See also* Kaiser Found. Health Plan, Inc. v. Abbott Labs., Inc., 552 F.3d 1033, 1037 (9th Cir. 2009) ("If a patent holder fails to bring an infringement action within forty-five days of receipt of a Paragraph IV notification, it loses the right to the thirty-month automatic stay ...").

58. 35 U.S.C. §§ 101, 102, 103 (2012).

59. *Id.* § 154(a)(1).

60. *Id.* § 271(a).

61. *Id.* § 153.

62. *Id.* § 154(a)(1).

63. *Id.* § 112.

64. *Id.* § 112(a).

65. *Id.* § 112(b).

claim ‘define[s] the scope of a patent grant’”<sup>66</sup> by identifying the “metes and bounds of the claimed invention.”<sup>67</sup>

A patentee may file suit for infringement against one who makes, sells or uses the patented invention.<sup>68</sup> “Victory in an infringement suit requires a finding that the patent claim ‘covers the alleged infringer’s product or process,’ which in turn necessitates a determination of ‘what the words in the claim mean.’”<sup>69</sup> The process of analyzing whether there has been patent infringement typically requires two steps. First, a court must construe or interpret the meaning of the claims.<sup>70</sup> While this starts with evaluating the claims themselves, the court may also look to a patents’ specification to the extent it assists in interpreting the meaning of claims.<sup>71</sup> Second, the court will compare defendant’s product or method to the patent and conclude whether there is an infringement (i.e., that there is a match, in layman’s terms).<sup>72</sup> Successfully proving infringement will afford the patentee the right to seek damages<sup>73</sup> and an injunction.<sup>74</sup> A finding of infringement does not necessarily guarantee victory for the patentee, however. A defendant may also attack the validity of the patent,<sup>75</sup> i.e., there is no liability for infringing an invalid patent.

#### *D. Liability for Frivolous Lawsuits*

Antitrust is not the only means by which the law attempts to curb frivolous litigation. Indeed, one may question why antitrust—which focuses on competition—is needed for such a task (or even appropriate). However, as maintained *infra*, antitrust liability is necessary in certain situations where other means of deterring frivolous litigation are likely to be insufficient—such as where frivolous

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66. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996).

67. U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINATION PROCEDURE (MPEP) §§ 2173, 2173.05(a), (Sept. 2012), *available at* , <http://www.uspto.gov/web/offices/pac/mpep/s2173.html>.

68. 35 U.S.C. § 271(a).

69. *Markman*, 517 U.S. at 374 (citations omitted).

70. *Id.* at 373.

71. *Philips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (“The claims, of course, do not stand alone. Rather, they are part of ‘a fully integrated written instrument,’ consisting principally of a specification that concludes with the claims. For that reason, claims ‘must be read in view of the specification, of which they are a part.’ As we stated in *Vitronics*, the specification ‘is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.’”) (citations omitted).

72. *IMS Tech., Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1429 (Fed. Cir. 2000).

73. 35 U.S.C. § 284.

74. *Id.* § 283.

75. *Id.* §§ 101–103 (requirements for patent validity).

litigation is likely to impede competition and the potential gains far exceed any penalty, cost, or fine imposed.

Various statutes and ethical rules attempt to deter frivolous litigation. For example, under the Model Rules of Professional Conduct, an attorney is not to file an action “unless there is a basis in law and fact for doing so that is not frivolous, which includes a good faith argument for an extension, modification or reversal of existing law.”<sup>76</sup> Pursuant to Rule 11 of the Federal Rules of Civil Procedure (“Rule 11”), an attorney filing an action in federal court must attest that the action is “not being presented for any improper purpose, such as to harass, cause unnecessary delay, or needlessly increase the cost of litigation,” and that all claims are “nonfrivolous.”<sup>77</sup> Litigation done for the purpose of causing delay has been found to be an “improper purpose” under Rule 11.<sup>78</sup>

Rule 11 not only prohibits affirmative misconduct, e.g., filing an action with an improper purpose, but also mandates a minimal amount of due diligence prior to initiating litigation.<sup>79</sup> Thus, pursuant to Rule 11, an attorney is required “to conduct a reasonable inquiry into the law and facts before filing a pleading in a court.”<sup>80</sup> In the context of patent infringement actions, the due diligence requirement of Rule 11 mandates, “at a minimum, that an attorney interpret the asserted patent claims and compare the accused device with those claims before filing a claim alleging infringement.”<sup>81</sup> Moreover, an attorney must “certify that the claims contained therein are not frivolous, legally unreasonable, without factual foundation, or asserted for an improper

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76. MODEL RULES OF PROF'L CONDUCT R. 3.1 (1983). *See also* RESTATEMENT OF THE LAW GOVERNING LAWYERS §§ 110, 170 (2000).

77. FED. R. CIV. P. 11(b). Another potential basis for awarding fees for frivolous lawsuits may be 28 U.S.C. §1927, a fee shifting statute titled “Counsel’s Liability for Excessive Costs.” Furthermore, fees or sanctions could be imposed under a court’s inherent power to control litigation. *E.g.*, *Chambers v. NASCO, Inc.*, 501 U.S. 32, 33 (1991); *Autorama Corp. v. Stewart*, 802 F.2d 1284, 1287–88 (10th Cir. 1986); *Adams v. Carlson*, 521 F.2d 168, 170 (7th Cir. 1975). However, each of these grounds has substantial limitations that make them unlikely deterrents.

78. *See, e.g.*, *Wright v. Tackett*, 39 F.3d 155, 158 (7th Cir. 1994) (finding improper purpose where plaintiff filed lawsuit just to delay foreclosure proceedings); *Pathe Computer Control Sys. Corp. v. Kinmont Indus., Inc.*, 955 F.2d 94, 97 (1st Cir. 1992) (finding timing of motion to transfer indicated a last minute effort to delay a likely adverse decision on the merits); *INVST Fin. Group v. Chem-Nuclear Sys., Inc.*, 815 F.2d 391, 402 (6th Cir. 1987); *Davis v. Veslan Enters.*, 765 F.2d 494, 500 (5th Cir. 1985); *In re Oximetrix, Inc.*, 748 F.2d 637, 644 (Fed. Cir. 1984).

79. *See Q-Pharma, Inc. v. The Andrews Jergens Co.*, 360 F.3d 1295, 1300 (Fed. Cir. 2004).

80. *Id.*

81. *Id.* at 1300–01.

purpose.”<sup>82</sup> However, Rule 11 is not likely to deter maintaining a frivolous action because courts have generally not interpreted the rule to proscribe “continuing a nonmeritorious lawsuit.”<sup>83</sup>

Patent law also attempts to deter frivolous litigation by granting courts the authority to award fees incurred in defending such actions. Pursuant to Section 285 of the Patent Act (“Section 285”), a court may award reasonable attorney’s fees in “exceptional”<sup>84</sup> cases, i.e., those involving bad faith, frivolous suits, vexatious litigation, or other types of misconduct effectuated in either litigation or in securing a patent.<sup>85</sup> Patent infringement litigation that is both objectively baseless and made in bad faith may be deemed “exceptional”<sup>86</sup> and thereby subject

82. *Id.* at 1300. *See also* *Judin v. United States*, 110 F.3d 780, 784–85 (Fed. Cir. 1997) (finding a Rule 11 violation where neither patentee nor counsel put forth reasonable pre-litigation effort to assess whether there was infringement, including attempting to obtain the alleged infringing product).

83. *See, e.g.,* *Hilton Hotels Corp. v. Banov*, 899 F.2d 40, 44–45 (D.C. Cir. 1990) (citing cases and holding that “Rule 11’s emphasis on the need to perform a ‘reasonable inquiry’ before ‘sign[ing]’ a ‘pleading, motion, or other paper’ suggests that the rule authorizes sanctioning an attorney only for unreasonably *filing* such a submission, not for *failing* to *withdraw* or to *amend* the submission when *postfiling* contingencies reveal it to be unfounded) (citation omitted); Julia K. Cowles, *Rule 11 of the Federal Rules of Civil Procedure and the Duty to Withdraw a Baseless Pleading*, 56 FORDHAM L. REV. 697, 704–05 (1988). *Cf. Highmark, Inc. v. Allcare Health Mgmt. Sys.*, 687 F.3d 1300, 1309 n.1 (Fed. Cir. 2012) (“[T]he inquiries under Rule 11 and EAJA [the Equal Access to Justice Act] look to the situation existing at the time a particular claim or representation was made, analyzing only the facts and law present at that time [sic] determine whether the claim or representation was justified.”). *But see* G. Wayne Merchant, II, *At What Point Does an Attorney Have A Duty to Dismiss a Lawsuit That May be a Meritless Claim?*, 27 J. LEGAL PROF. 233, 235 (2003) (discussing cases wherein attorneys were sanctioned under Rule 11 because they continued with lawsuits they knew to be frivolous).

84. 35 U.S.C. § 285.

85. *E.g., Highmark*, 687 F.3d at 1315–16, *cert. granted*, 134 S. Ct. 48 (Oct. 1, 2013) (“‘Litigation misconduct generally involves unethical or unprofessional conduct by a party or his attorneys during the course of adjudicative proceedings,’ and includes advancing frivolous arguments during the course of the litigation or otherwise prolonging litigation in bad faith.”) (citation omitted); *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989) (“Among the types of conduct which can form a basis for finding a case exceptional are willful infringement, inequitable conduct before the P.T.O., misconduct during litigation, vexatious or unjustified litigation, and frivolous suit.”) (citation omitted). The Supreme Court’s review of *Highmark* is limited to the issue of what is the appropriate level of deference on appeal of a district court’s findings that a case is “exceptional.” *See* Brief for Petitioner at i, *Highmark*, 134 S. Ct. 48 (Oct. 1, 2013) (No. 12-1163), available at <http://sblog.s3.amazonaws.com/wp-content/uploads/2013/07/No-12-Highmark-Cert-PetAppendix-Final.pdf>.

86. *E.g., Highmark*, 687 F.3d at 1308; *Brooks Furniture Mfg. v. Dutailier Int’l, Inc.*, 393 F.3d 1378, 1381 (Fed. Cir. 2005); *Phonometrics, Inc. v. Choice Hotels Int’l, Inc.*, 65 Fed Appx. 284, 285 (Fed. Cir. 2003). The appropriateness of the Federal’s Circuit’s standard for deciding when a case is “exceptional” is on appeal and will be decided this term by the Supreme Court. In *Icon Health & Fitness, Inc. v. Octane Fitness, Inc.*, 496 Fed. Appx. 57 (Fed. Cir. 2012), *cert. granted*, 134 S.Ct. 49 (Oct. 1, 2013), the Supreme Court

to an award of fees under Section 285.

While antitrust may not be the only means of deterring frivolous litigation, remedies for an antitrust violation—such as treble damages—may be quite substantial and thus more likely to deter such conduct, in contrast to violations of Rule 11 and Section 285 which only result in fee shifting and/or sanctions. Indeed, in markets where a monopolist may reap considerable profits by impeding competition—such as in pharmaceuticals—antitrust may play a significant role in preventing frivolous litigation.

### III. HATCH-WAXMAN CASES INVOLVING OBJECTIVELY BASELESS INFRINGEMENT

This section examines Hatch-Waxman litigation between a branded drug manufacturer with an approved NDA and one or more generic drug manufacturers that have filed an ANDA and have been sued for patent infringement. In each of these cases, the ANDA holder asserts that the infringement allegations are a sham and done solely to delay generic entry. The cases demonstrate that although the reasons why Hatch-Waxman litigation may be (or become) objectively baseless may vary, e.g., from a lack of effort in assessing infringement, to clear evidence of non-infringement, to evidence of bad faith and improper motive, such litigation has the potential to be anticompetitive by delaying generic competition.

Part A evaluates cases challenging an NDA's patent infringement allegations via antitrust sham litigation claims (or counterclaims), while Part B reviews cases contesting infringement assertions under Rule 11 and/or Section 285. Although sham litigation claims (or counterclaims) are not uncommon in Hatch-Waxman cases, they are often based on patents alleged to be invalid and/or unenforceable.<sup>87</sup> In

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will review the Federal Circuit's existing standard for determining whether conduct is "exceptional." While the Petitioner argues that the Federal Circuit's standard is not supported by the text of the statute and is contrary to its purpose, *see* Brief for Petitioner at 10, *Icon Health & Fitness, Inc. v. Octane Fitness, Inc.*, 134 S. Ct. 49 (Oct. 1, 2013) (No. 12-1184), even if the Supreme Court agrees and applies a more flexible and easier standard for finding a case as "exceptional," it will have a limited deterrent effect on filing and maintaining frivolous litigation since the statute only grants attorney's fees for "exceptional" cases.

87. *See, e.g., In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677 (2d Cir. 2009); *Kaiser Found. Health Plan, Inc. v. Abbott Labs, Inc.*, 552 F.3d 1033 (9th Cir. 2009); *Walker Process Equip., Inc. v. Food Machinery & Chem. Corp.*, 382 U.S. 172, 174 (1965) ("[T]he enforcement of a patent procured by fraud on the Patent Office may be violative of § 2 of the Sherman Act provided the other elements necessary to a § 2 case are present."). Similarly, litigation to enforce a patent known to be invalid may also violate the antitrust laws. For example, in *Handsguard, Inc. v. Ethicon, Inc.*, the court upheld a jury verdict



contrast, this article focuses on cases where sham litigation is predicated on baseless infringement assertions.<sup>88</sup> The article does not purport to be an exhaustive review of all such cases, but rather, evaluates cases considered to be illustrative of the types of situations where maintaining baseless litigation may be anticompetitive. And while the cases discussed assert that the action was a sham at the time the case was filed, as discussed *infra* Part IVA, this is a distinction without a difference. That is, there are similar anticompetitive concerns with maintaining baseless litigation as with filing such litigation, and no reason to treat such actions differently.

*A. Antitrust Sham Litigation Cases Predicated on Baseless Infringement*

The following are three Hatch-Waxman cases where antitrust claims (or counterclaims) were based on allegations that the underlying infringement actions were baseless. While the cases arise in different factual and procedural contexts, in each case the court agreed that the allegations or facts asserted plausibly supported a finding that the NDA holder's infringement litigation was a sham.

Sham litigation claims (or counterclaims) made in the Hatch-Waxman context must satisfy the same elements as all sham litigation claims. Thus, while Hatch-Waxman litigation certainly has its unique features, to succeed on a claim of antitrust sham litigation requires both: (a) demonstrating that the litigation is a sham and thereby not granted antitrust immunity under *Noerr-Pennington*; and (b) proving a substantive antitrust violation.

Recall that the filing of litigation to vindicate legal rights is typically afforded antitrust immunity. However, sham litigation that is both objectively baseless "in the sense that no reasonable litigant could realistically expect success on the merits," and is subjectively improper, i.e., "conceals 'an attempt to interfere directly with the business relationships of a competitor,'" <sup>89</sup> is not granted immunity. And while proving that litigation is a sham is often a formidable task, it certainly is not impossible. Indeed, it is worth emphasizing that courts have largely rejected efforts to immunize Hatch-Waxman litigation

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imposing antitrust liability for initiation and maintenance of an infringement action despite knowing that the patent was invalid. 743 F.2d 1282 at 1300 (9th Cir. 1984).

88. In a few of the cases discussed, sham litigation claims were predicated on both unenforceability of the patent as well as baseless infringement. See, e.g., *Nabi Biopharmaceuticals v. Roxane Labs, Inc.*, No. 2:05-CV-889, 2007 WL 894473 (S.D. Ohio Mar. 21, 2007).

89. *Prof'l Real Estate Invs. v. Columbia Pictures*, 508 U.S. 49, 60-61 (1993).

from antitrust liability due to certain features of its regulatory context. Thus, while a few courts have suggested that the filing of Hatch-Waxman litigation should be presumptively reasonable (and thus not a sham) due to the limited forty-five day period provided to branded drug manufactures to file suit in order to stay FDA approval of the generic for thirty months, these decisions have largely not been followed.<sup>90</sup>

### 1. *PhosLo*

*Nabi Biopharmaceuticals v. Roxane Labs*<sup>91</sup> was a suit involving PhosLo, a branded drug marketed by Nabi and approved by FDA to treat hyperphosphatemia, a condition causing the body to retain high levels of phosphate.<sup>92</sup> Nabi listed three patents for PhosLo in the Orange Book, including 6,576,665 ('665) which claimed a calcium acetate capsule with a bulk density of between 0.50 kg/L and 0.80 kg/

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90. For example, In *AstraZeneca AB v. Mylan Labs, Inc.*, Nos. 00 Civ. 6749, 03 Civ. 6057, 2010 WL 2079722 (S.D.N.Y. May 19, 2010), a Hatch-Waxman case involving omeprazole, the court suggested that patent litigation by a branded company would likely always be objectively reasonable and thereby not a sham:

[A]t the outset of Astra's case, Mylan gave Astra an objectively reasonable basis to sue: Mylan provided Astra notice of its Paragraph IV certification. This is an act of infringement under 35 U.S.C. § 271(e)(2)(A). The Court agrees with Astra that a reasonable plaintiff in a Hatch-Waxman case would be expected to know few details about the accused product at the outset of litigation and plaintiff's counsel may reasonably rely on discovery to learn the material details.

*Id.* at \*4 (citation omitted). However, as discussed *infra*, another judge in the same court came out with a very different conclusion in similar omeprazole patent litigation against a different generic manufacturer. *AstraZeneca AB v. Dr. Reddy's Labs, Ltd.*, No. 07 Civ. 6790(CM), 2010 WL 1375176 (S.D.N.Y. Mar. 30, 2010). Similarly, in *Celgene Corp. v. KV Pharms. Co.*, No. 07-4819 (SDW), 2008 WL 2856469 (D.N.J. July 22, 2008), a Hatch-Waxman litigation involving methylphenidate (an ADHD drug), the court suggested that filing infringement might always be objectively reasonable:

Because the Act has made the act of submitting an ANDA itself an act of infringement, in a Hatch-Waxman ANDA case, the attorney can conduct a reasonable and competent inquiry into the act of infringement by investigating whether a relevant ANDA has been filed. In the instant case, the Notice Letter provided sufficient basis for an attorney to reasonably believe that a relevant ANDA had been filed, and thus that an actionable act of infringement had occurred. Because submitting the ANDA itself is an act of infringement, and is therefore actionable, and because Celgene's Complaint predicates both of its two counts on that act of infringement, Celgene and its attorneys had no pre-filing obligation to investigate whether KV's methylphenidate drug actually infringed Celgene's patents. Because there is no dispute that KV submitted an ANDA which constitutes an act of infringement, and because KV states that, prior to filing suit, Celgene had received the Notice Letter which gave notice of the ANDA submission, this Court concludes that Celgene's pre-filing infringement investigation was reasonable under the circumstances.

*Id.* at \*3. These cases, however, have largely not been followed.

91. 2007 WL 894473.

92. *Id.* at \*7.

L.<sup>93</sup> After Roxane filed an ANDA for generic PhosLo and submitted a paragraph IV certification on the '665 patent, Nabi sued Roxane for patent infringement.<sup>94</sup>

In response to the infringement suit, Roxane filed a monopolization counterclaim alleging antitrust sham litigation predicated on baseless infringement claims as well as an unenforceable patent.<sup>95</sup> According to Roxane, Nabi's conduct in filing and "contin[uing] to maintain the current action" was objectively baseless because, prior to the litigation, Roxane provided Nabi with "clear evidence" that its generic did not infringe Nabi's patents.<sup>96</sup> Specifically, Roxane contended that prior to the litigation, it provided samples of its generic to Nabi that unequivocally demonstrated non-infringement.<sup>97</sup> Moreover, as evidence of bad faith, Roxane highlighted Nabi's refusal to provide Roxane with the results of any of its analysis of Roxane's samples.<sup>98</sup> And while Nabi filed a motion to dismiss Roxane's monopolization counterclaim, the court denied the motion, concluding that Roxane's allegations, if true, were sufficient to support an antitrust claim.<sup>99</sup>

## 2. *Neurontin*

*In re Neurontin Antitrust Litigation*<sup>100</sup> concerned gabapentin, an anti-epilepsy drug marketed by Warner-Lambert as Neurontin.<sup>101</sup> Warner-Lambert claimed patents on the drug as well as on various uses and processes involving the drug.<sup>102</sup> Several generic manufacturers

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93. *Id.* at \*1.

94. *Id.* at \*3.

95. *Id.* at \*1–2. The court also held that Nabi made sufficient factual assertions to support its claims that the patent was unenforceable due to fraud on the patent office and that enforcement of such patent could state an antitrust claim. *Id.* at \*4–5.

96. *Id.* at \*1, \*3.

97. *Id.* at \*3. According to Roxane, the information it provided to Nabi prior to litigation "demonstrated that Roxane's proposed calcium acetate capsules are made from calcium acetate with a bulk density outside of the range claimed in the 665 patent and utilizing untableted powder within a capsule, not compressed into a caplet as required by the claims of the 665 patent." *Id.*

98. *Id.* at \*4.

99. *Id.* at \*4 ("[B]ecause [the] counterclaims allege that the lawsuit filed... is objectively baseless and conceals an attempt to interfere directly with the business relationships of a competitor, the counterclaims adequately state a claim and should not be dismissed under Fed. R. Civ. P. 12(b)(6).").

100. Nos. 02-1830 (FSH), 02-2731 (FSH), 02-5583 (FSH), 2009 WL 2751029 (D.N.J. August 28, 2009).

101. *Id.* at \*2. Although the drug has been approved by the FDA for epilepsy since 1993, its primary use was off-label for various neurodegenerative conditions, such as Parkinsons, ALS. *Id.*

102. *Id.* at \*1. For example, patent 4,894,476 ('476) claimed gabapentin monohydrate;

filed ANDAs with paragraph IV certifications, and Warner-Lambert promptly commenced patent litigation against all of them.<sup>103</sup> In 2003, after several years of litigation, summary judgment of non-infringement was granted on the most relevant patents.<sup>104</sup>

Not long after the summary judgment decision, antitrust litigation was commenced by direct purchasers of Neurontin.<sup>105</sup> The direct purchasers alleged, *inter alia*, that Warner-Lambert's patent litigation was a sham and part of an "overall scheme to monopolize the market for gabapentin anhydrous products by forestalling, if not completely preventing, generic competition."<sup>106</sup> In particular, several of the infringement actions were challenged as being objectively baseless and made in bad faith.<sup>107</sup>

Warner-Lambert filed a motion to dismiss, contending that its infringement actions were immune under *Noerr-Pennington*,<sup>108</sup> and that plaintiffs failed to plead sufficient facts to support a monopolization claim.<sup>109</sup> The court disagreed and denied the motion.<sup>110</sup> First, the court rejected Warner-Lambert's immunity argument, noting that sham litigation is a well-recognized exception to *Noerr-Pennington* immunity.<sup>111</sup> Second, the court held that the

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patent 5,084, 479 ('479) claimed the use of gabapentin anhydrous to treat neurodegenerative diseases, and 6,054,482 ('482) claimed a process for developing low-lactum gabapentin. *Id.*

103. *Id.* at \*2.

104. *Id.* at \*3. For one of the patents, Warner-Lambert did not even oppose summary judgment, effectively conceding non-infringement. *Id.* at \*6 n.20.

105. *See id.* \*3.

106. *Id.* at \*4. The overall scheme included:

- (1) procuring two additional patents that it improperly listed in the Orange Book;
- (2) manipulating the patent approval process so that a third patent with claims so limited that they are impossible to accurately measure or distinguish from the prior art so that the patent could be used to delay generic entry; (3) filing and prosecuting multiple sham lawsuits on these patents that no reasonable litigant could have expected to succeed; and (4) engaging in fraudulent off-label promotion to convince doctors to prescribe Neurontin for uses for which it was not approved.

*Id.*

107. *Id.* at \*6. Specifically, it was alleged that: (i) the '476 patent litigation was baseless because the generics sought approval for a gabapentin anhydrous formulation rather than the patented gabapentin monohydrate formulation; (ii) the lawsuits on the '479 patent were baseless because the generics were not seeking approval for the use claimed by that patent (a use which was not approved by FDA); and (iii) the '482 patent litigation was baseless because the patent's claims "are formulated so narrowly, it is not possible to determine whether generic products would actually infringe the patent." *Id.* at. *Accord In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 361–64 (D.N.J. 2009) (discussing plaintiff's allegation of baseless patent litigation based on Gabapentin drug).

108. *See supra* Part II.A.

109. *Neurontin*, 2009 WL 2751029, at \*21–22.

110. *Id.* at \*23.

111. *Id.* at \*21 ("Warner-Lambert correctly argues that litigation to enforce its rights

plaintiffs alleged sufficient facts to support their antitrust claims.<sup>112</sup>

### 3. *Wellbutrin XL*

Most recently, the court in *In re Wellbutrin XL Antitrust Litigation*<sup>113</sup> addressed antitrust sham litigation in a summary judgment context. *Wellbutrin XL* involved Hatch-Waxman litigation for a controlled release formulation for the antidepressant bupropion hydrochloride, which is marketed by Biovail as Wellbutrin XL.<sup>114</sup> Biovail listed two patents for the controlled release formula: 6,096,341 ('341) and 6,143, 327 ('327).<sup>115</sup> Four generic manufacturers filed ANDAs for the drug with paragraph IV certifications, and Biovail promptly filed infringement actions against each.<sup>116</sup> All four patent lawsuits settled.<sup>117</sup> Thereafter, direct and indirect purchasers of Wellbutrin XL filed antitrust litigation against Biovail, alleging numerous anticompetitive acts including sham litigation.<sup>118</sup> Biovail moved for summary judgment on various grounds, arguing *inter alia* that its infringement action against one of the generics—Abrika—was *per se* reasonable (and hence not a sham) because Abrika refused to

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under its gabapentin patents is presumptively immune from antitrust scrutiny under the *Noerr-Pennington* doctrine. However, Warner-Lambert is not entitled to such immunity if Plaintiffs can establish that the '476, '479, and '482 infringement actions were 'sham litigation.'").

112. *Id.* Specifically, Plaintiffs averred that Defendants knew or recklessly disregarded the fact that the '476 patent was not infringed by the generic's drug, and yet still initiated infringement actions. *Id.* With respect to the '479 patent actions, Plaintiffs claimed that Warner-Lambert brought suit against the generic manufacturers without evidence of knowledge and intent to induce infringement, while knowing that none of the generic applicants sought approval to market generic gabapentin to treat neurodegenerative diseases. *Id.* Finally, Plaintiffs argued that they have sufficiently alleged that "no reasonable litigant would believe that the ['482 patent's claims] could ultimately be upheld as valid, definite, and/or infringed, [b]ecause of the inability to measure chloride ions from a mineral acid at the low levels specified by the '482 patent, or to distinguish the level of chloride ions from a mineral acid in the claim from the prior art." *Id.* at \*21 (internal quotations marks omitted).

113. *In re Wellbutrin XL Antitrust Litig.*, Nos. 08–2431 (direct), 08–2433 (indirect), 2012 WL 1657734 (E.D. Pa. May 11, 2012).

114. *Id.* at \*1–2. Prior formulations of Wellbutrin included a rapid release formulation that was to be taken three times a day, Wellbutrin IR, and a sustained release formulation, Wellbutrin SR. *Id.* The later was brought to market in 1997 and was also the subject of antitrust litigation. *See, e.g., In re Wellbutrin SR Antitrust Litig.*, No. Civ.A. 04–5525, Civ.A. 04–5898, Civ.A. 05–396, 2006 WL 616292 (E.D. Pa. Mar. 9, 2006).

115. *Wellbutrin*, 2012 WL 1657734 at \*3.

116. Impax, Waton, Anchen, and Abrika were the four generics that filed ANDAs. Although the '327 patent was listed in the Orange book and was claimed to be infringed in some of the ANDA litigation, the infringement claims on the '327 were eventually dropped in all suits. *Id.* at \*5 n.8. Only the '341 patent was at issue in the antitrust cases. *Id.* at \*5

117. *Id.* at \*6.

118. *Id.* at \*1. The suit also was brought against GlaxoSmithKlein, which was the distributor of Wellbutrin XL. *Id.*

supply it with samples, and thus Biovail was unable to do a proper infringement analysis prior to filing suit.<sup>119</sup>

The court rejected Biovail's argument that its conduct should be *per se* reasonable.<sup>120</sup> Rather, according to the court, while inability to obtain a sample may excuse a patentee from conducting a proper infringement analysis prior to filing suit, the litigation could still be a sham if Biovail's interpretation of its patent claims was unreasonable.<sup>121</sup> Thus, the Court not only rejected immunity for filing the lawsuit, but did so even when a pre-litigation infringement analysis was not possible due to the generic's conduct. Nevertheless, the Court did grant summary judgment for patentees in all four infringement actions—including the Abrika action<sup>122</sup>—after concluding that the facts did not support the plaintiffs' theory.<sup>123</sup>

These cases demonstrate that courts recognize antitrust claims for filing sham litigation in the Hatch-Waxman regulatory context. Moreover, although the cases focused on the *filing* of the suit, it is evident from the decisions that *maintaining* the litigation may be considered in evaluating anticompetitive effects.

#### *B. Frivolous and/or "Bad Faith" Cases Predicated on Baseless Infringement*

The cases discussed in this part involve requests for fees in defending frivolous or "bad faith" litigation, brought pursuant to Rule

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119. *Id.* at \*13.

120. *Id.* at \*17.

121. *Id.* at \*13 ("The defendants argue as a preliminary matter that in the Hatch-Waxman context, they had a reasonable basis to institute suit against Abrika because Abrika did not provide pre-filing access to its ANDA. . . . This argument only holds weight, however, if this Court agrees that the defendants could reasonably expect success on the merits of their claim construction argument . . . .") (citations omitted).

122. *Id.* at \*17. In the Abrika action the court granted summary judgment for Biovail because it concluded that the litigation—even if it were a sham—did not delay Abrika from launching its generic and thus did not cause anticompetitive harm. *Id.* Specifically, the thirty month stay caused by the allegedly baseless litigation expired over a year before Abrika obtained FDA approval for its generic. Consequently, the court concluded that the litigation was not the cause of Abrika's delay and thus, Abrika could not have sustained competitive harm due to the litigation. *Id.*

123. *Id.* Specifically, for three of the infringement actions, the issue was primarily whether Biovail's interpretation of claims in the '341 patent were objectively baseless. Although it found that Biovail's interpretations were questionable, the court concluded that they were not objectively baseless and thereby not a sham. *Id.* at \*8–9, \*11, \*19. On the fourth infringement action, the court did not directly address whether the litigation was a sham, but rather granted summary judgment on grounds that even if it were, there was insufficient evidence of anticompetitive harm. *Id.* at \*17. While the court believed that patentees had a "colorable legal argument" in support of its infringement claims (and thus was not baseless), it declined to make a finding on that issue. *Id.* at \*15, \*17.

11 and/or Section 285. Because Rule 11 and Section 285 cases may also be based upon objectively baseless infringement claims—and thus may potentially support antitrust claims as well—they are worth examining.

1. *Prilosec OTC*

*AstraZeneca v. Dr. Reddy's*<sup>124</sup> concerned an over-the-counter version of the popular heartburn drug omeprazole magnesium, marketed by AstraZeneca as Prilosec OTC. AstraZeneca listed two patents in the Orange Book for the drug, which claimed a particular crystalline formulation of omeprazole magnesium and the process used in manufacturing it.<sup>125</sup> Dr. Reddy's (among others) submitted an ANDA with a paragraph IV certification asserting, *inter alia*, that its ANDA did not infringe the patents listed for Prilosec OTC.<sup>126</sup> After two years of discovery, during which Dr. Reddy's provided samples of its generic and access to its Drug Master File, as well as responses to AstraZeneca's deposition and interrogatory requests, the court granted summary judgment of non-infringement.<sup>127</sup>

Thereafter, the court granted Dr. Reddy's motion for fees under Section 285, citing various grounds evidencing that the case was frivolous and "nothing more than an effort to keep a legitimate competitor out of the market on flimsy-to-nonexistent grounds."<sup>128</sup> First, the Court found AstraZeneca's interpretation of its claims wholly unreasonable.<sup>129</sup> Specifically, the court concluded that despite the patent being "easy to understand," the patentee put forth a "tortured claim construction," arguing for an interpretation of its claims that was "inherently self-contradictory" and which "made "absolutely no sense."<sup>130</sup> Second, the court believed that non-infringement could easily be determined via a straight-forward comparison of the branded product (and process) with the generic product (and process).<sup>131</sup> Third,

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124. *AstraZeneca AB v. Dr. Reddy's Labs, Ltd.*, No. 07 Civ. 6790 (CM), 2010 WL 1375176 (S.D.N.Y. Mar. 30, 2010).

125. *See id.* at \*2–3.

126. *See id.* at \*2.

127. *Id.* at \*2–3.

128. *Id.* at \*5, \*6, \*9. The court also suggested that the action may violate Rule 11. *Id.* at \*6.

129. *AstraZeneca*, 2010 WL 1375176 at \*8.

130. *Id.* at \*8.

131. *Id.* at \*1. ("That the process used by defendants to create omeprazole magnesium did not read on plaintiffs' patent was apparent from a reading of the patent and a description of defendants' process for creating the popular drug Prilosec OTC. Indeed, defendants' products and process are in key respects exactly the opposite of what plaintiffs claim in their patents.") The court also found that non-infringement of the formulation patents was simple

according to the court, notwithstanding substantial evidence of non-infringement (both pre-litigation and early on in the suit) and an offer by Dr. Reddy's of a "reasonable way to resolve [the] lawsuit expeditiously," AstraZeneca continued to litigate and sought "wide-ranging discovery."<sup>132</sup> Fourth, the court found that up to and including summary judgment, AstraZeneca "never put forward any evidence of infringement and any reasonably party would have known that [the] action should have been terminated early."<sup>133</sup> Finally, the court determined that the suit was brought and maintained solely for an improper purpose, i.e., to deter generic competition.<sup>134</sup>

## 2. *Amrix*

*In re Cyclobenzaprine hydrochloride Extended Release Capsule Patent Litigation*,<sup>135</sup> involved cyclobenzaprine hydrochloride capsules, a skeletal muscle relaxant. The drug is marketed as Amrix, and rights to the drug are shared by several companies ("patentees").<sup>136</sup> Two patents were listed in the Orange Book for Amrix: 7,387,793 ('793) (claiming an extended release dosage form of skeletal muscle relaxants), and 7,544,372 ('372) (claiming a method of relieving muscle spasms with the extended release formulation).<sup>137</sup> Various generic manufacturers submitted ANDAs for the drug, including Anchen.<sup>138</sup> Upon receiving paragraph IV certifications, patent litigation was initiated against each company.<sup>139</sup> In granting summary judgment of non-infringement for Anchen, the court emphasized that not only did patentees fail to provide *any* evidence as to Anchen's infringement, but even admitted that the ANDA did not infringe the

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to ascertain because there was "*no evidence whatever* that DRL makes or uses a salt with the requisite degree of crystallinity" and that AstraZeneca's experts did not "suggest any reason why the process and apparatus used by DRL would result in a finished product containing 70%-or-more crystalline omeprazole magnesium." *Id.* at \*5 (emphasis added).

132. *Id.* at \*1, \*6.

133. *AstraZeneca*, 2010 WL 1375176 at \*4. *See also Id.* at \*6 ("All the discovery in the world would not give Astra a stronger argument against dismissal ...." (Slip op. at 31 n. 5.) But of course, "all the discovery in the world" is what Astra wanted-and it wanted that discovery in order to keep defendants' product off the market for as long as possible.").

134. *Id.* at \*1 ("It was obvious from very early on that plaintiffs had brought and were maintaining this lawsuit in a desperate effort to keep any competing product from hitting the shelves-even if the competing product was not an infringing product.").

135. *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 794 F. Supp. 2d 517 (D. Del. 2011), *rev'd on other grounds*, 676 F.3d 1063 (Fed. Cir. 2012).

136. *Id.* at 523.

137. *See id.* at 524-25.

138. *See id.* at 522.

139. *Id.* at 523.



patents.<sup>140</sup>

Shortly after being granted summary judgment, Anchen filed a Section 285 motion for attorney's fees, arguing that the infringement action was baseless and initiated solely to deter generic competition by "improperly invoke[ing] an FDA stay of approval of Anchen's ANDA."<sup>141</sup> While the court disagreed that the evidence demonstrated that the litigation was frivolous at the time filed, *it agreed that it became frivolous at a later time.*<sup>142</sup> In particular, the court found significant that patentees failed to provide any evidence of infringement and even conceded that Anchen's ANDA did not infringe.<sup>143</sup> The court concluded that the case was "exceptional" and granted fees, holding that there was sufficient evidence that "the suit became unjustifiable once plaintiff's declined to acknowledge that there was no need to maintain the suit."<sup>144</sup>

As with the cases discussed in the prior section, these cases evidence situations where baseless litigation was brought and maintained to delay competition. And while antitrust claims were not made in these cases, they potentially could have been. Finally, it is worth emphasizing that the *Amrix* decision made clear that even if a suit was not baseless at the time filed, if it becomes so at a later time, a party has a duty to dismiss the suit or else face potential liability for failing to do so.

#### IV. ANALYSIS

As evidenced by the cases discussed, filing and maintaining baseless lawsuits may have anticompetitive effects. And while the cases focused primarily on initiation of litigation, it was recognized that maintaining the actions was also improper. Indeed, where maintaining baseless litigation has anticompetitive effects, there is no compelling rationale for creating a legal distinction between the filing

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140. *Id.* at 523 n.3. In contrast, the court concluded that several of the other generic's formulations did infringe the listed patents. *See id.*

141. *In re Cyclobenzaprine hydrochloride Extended-Release Capsule Patent Litig.*, Civ. No. 09-MD-2118-SLR, 2012 WL 95592, at \*1-2 (D. Del. Jan 12, 2012).

142. *Id.* at \*3 n.8. In concluding that filing suit was not a sham, the court appeared to find significant that Anchen refused to provide ANDA samples prior to litigation due to purported confidentiality concerns and an inability to come to terms on a confidentiality agreement. *See id.* at \*2. The court thus seemed sympathetic to patentees assertion that that they had no choice but to sue. *See id.*

143. *Id.* at \*2 n.4.

144. *Id.* at \*3 n.8. Although patentees attempted to justify maintaining the suit to "police" against possible ANDA reformulations by Anchen, the court rejected this argument, concluding that there were existing safeguards for such concerns. *Id.* at \*1-3.

and maintaining of a baseless action.<sup>145</sup> And in situations where a litigant is able to offer a questionable but potentially legitimate basis for filing an action (thereby making the suit unlikely to qualify as a sham), the greater need for imposing liability for continuing to litigate after it becomes clear that the action is meritless. Consequently, this section provides the argument for antitrust liability for maintaining baseless litigation.

*A. Antitrust Sham Litigation for Maintaining Baseless Litigation is Good Policy*

There are several justifications for imposing antitrust liability for continuing to litigate a baseless action for anticompetitive purposes. And where such litigation may cause anticompetitive effects—such as in Hatch-Waxman litigation—the potential for incurring antitrust liability may be an important deterrent.

First, antitrust liability is needed because laws prohibiting frivolous and bad faith litigation (such as Section 285 or Rule 11), are inadequate deterrents in many situations. Granting fees under Section 285 is largely within a court's discretion, and thus a court may decline to impose fees in even egregious circumstances.<sup>146</sup> Similarly, Rule 11 is not only discretionary, but several courts have interpreted it as only governing the *filing* of litigation and thereby rejected its application to conduct done in the course of litigation (including continuing to

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145. The best argument for imposing such a distinction would be if the filing of the action has a particular anticompetitive effect, separate and apart from maintaining the action. In the Hatch-Waxman context, this may be the case, as the filing of an infringement action upon receiving a paragraph IV certification triggers a thirty-month stay of FDA approval for the generic. 21 U.S.C. § 355(j)(5)(B)(iii). Moreover, the effect of dismissing the action on the thirty-month stay is not clear—which obviously impacts any anticompetitive effect of both filing and maintaining the litigation. *Compare In re Terazosin Hydrochloride Antitrust Litig.*, 335 F. Supp. 2d 1336, 1344 (S.D. Fla. 2004) (“A dismissal of the Hatch-Waxman infringement lawsuit lifts the 30 month stay.”), *with Endo Pharms. v. Mylan Techs.*, No. 11–220–GMS, 2013 WL 936452, at \*5 (D. Del. Mar. 11, 2013) (concluding in dicta that dismissal of Hatch-Waxman litigation will not extinguish the 30 month stay, since “[i]f Congress had wished the thirty month stay to be extinguished upon a dismissal without prejudice, it would have said as much.”). In 1999, the FDA proposed a rule that included extinguishing the 30 month stay upon dismissal of the patent litigation, but the proposal was withdrawn. *See* 180-Day Generic Exclusivity for Abbreviated New Drug Applications, 64 Fed. Reg. 42873, 42886 (proposed Aug. 6, 1999) (withdrawn in 67 Fed. Reg. 66593 (Nov. 1, 2002)).

146. *See, e.g., Raylon, LLC v. Complis Data Innovations, Inc.*, 700 F.3d 1362 (Fed. Cir. 2012), where the Federal Circuit reversed a District Court's denial of fees under Rule 11 and Section 285, finding that patentees' claims construction was clearly frivolous and unreasonable and neither supported by any part of the patent (*e.g.* claims, specification, preferred embodiment) nor the prosecutorial history. *See infra* Part IV.B,

maintain a baseless action).<sup>147</sup> Moreover, the remedies available under these provisions—mostly payment of defendant's fees and costs—are not particularly onerous and thus not likely to discourage frivolous litigation. As monopoly profits may be quite large, a firm may well be quite content risking having to pay fees and even sanctions (in contrast to the risk of treble damages for antitrust violations).

Second, to the extent that continuing to litigate a baseless action is anticompetitive, there is no rational basis for only imposing liability on the filing of the action but not on maintaining it. And where the litigation circumvents legislative policies, such as those created by the Hatch-Waxman Act, it should be prevented to the fullest extent possible. Thus, imposing liability on both filing and maintaining baseless, anticompetitive litigation would likely have the favorable effect of further deterring such deleterious conduct.

Third, successfully proving an antitrust claim is a difficult task, requiring not only demonstrating anticompetitive effects in most cases, but also various procedural hurdles. Consequently, concerns that imposing antitrust liability for maintaining baseless litigation could “open the floodgates” to additional antitrust litigation is unwarranted.<sup>148</sup> Indeed, outside of the context of the Hatch-Waxman Act (or a similar type of regulatory scheme), proving anticompetitive effects of sham litigation may well be difficult.

### *B. Evaluating Cases for Potential Antitrust Liability*

While antitrust liability should be imposed against companies which maintain anticompetitive, frivolous lawsuits, determining whether a particular action is baseless and anticompetitive may be quite difficult. Indeed, there may be significant legal and practical difficulties in establishing a *prima facie* antitrust claim, much less proving it. Nevertheless, by focusing on Hatch-Waxman cases, this section suggests several potential criteria that may assist in identifying appropriate cases.

The first criterion evaluated is the litigant's efforts (or lack thereof) in ascertaining infringement prior to filing suit. If a patentee

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147. See, e.g., *Thomas v. Capital Sec. Servs. Inc.*, 836 F.2d 866, 874 (5th Cir. 1988); *Gaiardo v. Ethyl Corp.*, 835 F.2d 479, 484 (3d Cir. 1987); *Pantry Queen Foods v. Lifschultz Fast Freight, Inc.*, 809 F.2d 451, 454 (7th Cir. 1987); *Oliveri v. Thompson*, 803 F.2d 1265, 1274 (2d Cir. 1986).

148. It is possible that antitrust liability for maintaining baseless litigation might result in additional antitrust litigation to the extent that it addresses statute of limitations problems. That is, in cases where the filing of a lawsuit is the sole alleged anticompetitive act and is outside the limitations period, the act of maintaining the action might save the claim from dismissal (assuming at least some of the litigation is within the limitations period).

failed to take reasonable steps to evaluate infringement prior to litigation, this may be indicative that the action was filed (and maintained) for an improper purpose. For example, the court in *In re Neurontin Antitrust Litigation* denied a motion to dismiss the antitrust claim in part due to allegations that the patentee never tested or examined the allegedly infringing product prior to filing suit.<sup>149</sup>

Second is examining whether a patentee continuously insists upon an interpretation of its patent claims that is nonsensical, wholly unsupported, or contradicted by either the patent's specification or its own assertions made before the P.T.O. For example, *Raylon v. Complus Data*<sup>150</sup> involved Raylon's patent for a hand-held ticketing device that contained its own internal keypad and printer and included a display that was "pivotally mounted on" the device.<sup>151</sup> The patent

149. *In re Neurontin Antitrust Litig.*, Nos. 02-1830 (FSH), 02-2731(FSH), 02-5583(FSH), 2009 WL 2751029, at \*23 (D.N.J. Aug. 28, 2009). *Cf.* *Eon-Net LP v. Flagstar Bancorp.*, 653 F.3d 1314, 1328 (Fed. Cir. 2011) (finding Rule 11 sanction where the patentee "failed to perform a pre-suit investigation."); *Judin v. United States*, 110 F.3d 780, 784–85 (Fed. Cir. 1997) (Rule 11 sanctions against patentee based in part on fact that patentee never attempted to obtain a copy of the alleged infringing product); *Hoffmann-La Roche, Inc. v. Genpharm, Inc.*, 50 F. Supp. 2d 367, 380 (D. N.J. 1999) ("The resolution of the question whether plaintiffs' suit is objectively baseless as to Genpharm involves the determination of whether plaintiffs undertook a reasonable investigation before filing suit, whether plaintiffs knew or should have known that Genpharm had not infringed the Syntex process patents, and whether a reasonable litigant could have realistically expected success on the merits at the time the suit was filed.").

150. *Raylon, LLC v. Complus Data Innovations*, 700 F.3d 1362 (Fed. Cir. 2012).

151. *Id.* at 1364–65 ("Claim 1 [of US patent No. 6,655,589] is representative of the patented system:

1. A system for investigating an identification of a person and for issuing tickets, the identification comprising a card having a computer readable magnetic tape secured on the card, the computer readable magnetic tape containing pertinent data relating to the person displayed on the identification card, said system being connectable to a computer for transmitting data between said system and the computer, said system being connectable to a data cable of a computer, said system comprising:

a housing having an interior, said housing having an elongated slot for selectively receiving the identification card, said housing having an elongated aperture providing access into said interior of said housing;

an input assembly for inputting data about a person, said input assembly being mounted on said housing, said input assembly including a data reading means for reading the computer readable magnetic tape on the identification card;

a transceiver assembly for remotely communicating with a computer, said transceiver assembly being mounted in said interior of said housing;

a display for displaying data entered into said input assembly, *said display being pivotally mounted on said housing*;

included a drawing that illustrated the invention's preferred embodiment, which was comprised of (among other things) a rectangular body with buttons for entering data, a location where tickets could be printed out, and a separate display attached to the device.<sup>152</sup> Raylon filed patent infringement actions against various software and hardware manufacturers of hand-held ticketing devices.<sup>153</sup> In defending the lawsuits, several defendants countered that their products could not infringe on Raylon's patent because their devices had rigid, fixed-mounted displays that could not be pivoted.<sup>154</sup> Raylon did not contest that defendants' products contained fixed-mounted, non-pivoting displays, but nonetheless maintained that defendants' devices infringed its patents because those devices could be manually pivoted, i.e., by the person holding the device.<sup>155</sup>

The District Court rejected Raylon's arguments as one which "stretch[es] the bounds of reasonableness," because it was unsupported by the evidence and would essentially ignore the "pivotally mounted" limitation of the patent.<sup>156</sup> Nevertheless, the District Court denied defendant's motion for sanctions and fees under Rule 11 and Section 285.<sup>157</sup> On appeal, the Federal Circuit reversed, holding that Raylon's interpretation of "pivotally mounted" was "frivolous" and "unreasonable" because the patent's claims, specifications, and preferred embodiment all clearly "show[] a display that is mounted to pivot relative to the housing on which it is attached."<sup>158</sup> Moreover, the

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a printer assembly being mounted in said interior of said housing for printing a ticket; and wherein said printer assembly includes

a substrate for receiving indicia, said substrate including an end extendable through said elongated aperture in said housing,

a printer means for printing indicia on said substrate, and means for advancing said substrate with respect to said printer means such that substrate is advanced through said elongated aperture in said housing when said printer means prints indicia on said substrate. Independent system claims 16 and 17 also recite a display being pivotally mounted on said housing limitation.") (citations omitted) (internal quotation marks omitted).

152. *See id.* at 1363–64.

153. *See id.* at 1363.

154. *See id.* at 1366.

155. *Id.* at 1365 ("In other words, under Raylon's theory of infringement a display with a fixed-mounted screen meets the 'pivotally mounted on said housing' limitation when the user pivots the device by moving his elbow, wrist, or other joint.").

156. *Id.* at 1365–66.

157. *Id.* at 1366.

158. *Id.* at 1367–69 ("Applying the objectively reasonable standard, we agree with defendants that Raylon's claim construction (and thus infringement contentions) were

Federal Circuit concluded that Raylon's construction was unsupported by the patent prosecution history (made before the P.T.O) and "does not conform to the standard canons of claims construction."<sup>159</sup>

Third is examining whether a patentee inexorably asserts infringement, even after discovery and evaluation of the accused product(s) or method(s) substantiate non-infringement. For example, in *AstraZeneca v. Dr. Reddy's*, the court was critical of AstraZeneca's continued position that Dr. Reddy's generic product infringed its formulation patent despite substantial evidence that Dr. Reddy's formulation was not 70% crystalline, as required by the asserted patent.<sup>160</sup> Similarly, the court in *In re Cyclobenzaprine Hydrochloride Extended Release Capsule Patent Litigation* granted fees under Section 285 in part because patentee maintained its lawsuit despite failing to

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frivolous. . . . Raylon's claim construction of 'display pivotally mounted on said housing' is a prime example of a construction that falls below this threshold. Raylon, throughout the litigation, argued that this term should be construed as requiring a 'display being capable of being moved or pivoted *relative to the viewer's perspective*.' Its construction encompasses any portable device with a display, regardless of how it is mounted to the housing . . . .

[Moreover], [t]hroughout the specification, the patentee describes the invention as containing a display that 'is pivotally mounted on the housing.' A display pivotally mounted on the housing is even identified by the patentee as one of the important features of the invention. Figure 1, the only schematic of the preferred embodiment, shows a display that is mounted to pivot relative to the housing on which it is attached.") (citations omitted).

159. *Id.* at 1369. *Accord* Eon-Net LP v. Flagstar Bancorp, 653 F.3d 1314, 1326 (Fed. Cir. 2011) ("[B]ecause the written description clearly refutes Eon-Net's claim construction, the district court did not clearly err in finding the Eon-Net pursued objectively baseless infringement claims."); *Phonometrics v. Choice Hotels Int'l, Inc.*, No. 02-1360, 2003 WL 2008126, at \*1 (Fed. Cir. April 29, 2003) ("[I]t was clear after we issued the claim construction in *Northern Telecom* that Choice Hotels did not infringe U.S. Patent No. 3,769,463 ('the '463 patent'). The district court thus concluded that [b]ecause Plaintiff continued to litigate this case knowing that its claim could not meet the standard for infringement of the '463 patent articulated by the Federal Circuit, this case is exceptional. . . .") (internal quotation marks omitted).

160. *AstraZeneca AB v. Dr. Reddy's Labs., Ltd.*, No. 07 Civ. 6790(CM), 2010 WL 1375176, \*5 (S.D.N.Y. Mar. 30, 2010). *Accord* *Nabi Biopharmaceuticals v. Roxane Labs.*, No. 2:05-CV-889, 2007 WL 894473, \*3 (S.D. Ohio Mar. 21, 2007) (refusing to dismiss a sham litigation claim against Nabi where the court found that Roxane provided samples and documents that "demonstrated that Roxane's proposed calcium acetate capsules are made from calcium acetate with a bulk density outside of the range claimed in the 665 patent and utilizing untabletted powder within a capsule, not compressed into a caplet as required by the claims of the 665 patent."). In contrast, where a patentee voluntarily dismisses an infringement action after discovery indicated non-infringement, a court is less likely to find that the litigation was a sham. *See, e.g., Kaiser Found. Health Plan v. Abbott Labs., Inc.*, 552 F.3d 1033, 1047 (9th Cir. 2012) ("It is true that Abbott was litigious, but to some degree its litigiousness was a product of Hatch-Waxman. Abbott filed suit quickly in order to preserve its rights under Hatch-Waxman, but it did not persist in litigating when it became obvious that the suits were baseless."); *Q-Pharma, Inc. v. The Andrews Jergen Co.*, 360 F.3d 1295 (Fed. Cir. 2005); *Hoffmann-La Roche, Inc. v. Invamed, Inc.*, 213 F.3d 1359 (Fed. Cir. 2000).

provide *any* evidence of infringement as to certain claims—even as late as trial.<sup>161</sup>

Fourth, litigation misconduct may evince that the action was initiated and maintained for an improper purpose. For example, in *AstraZeneca v. Dr. Reddy's*, one factor in the court's awarding of fees was patentee's discovery abuses, i.e., its "wide-ranging" discovery requests which were a mere "fishing-expedition" done for the purpose of deterring competition.<sup>162</sup> Similarly, engaging in a pattern of dubious litigation may suggest an improper purpose, particularly when the allegations made in the various actions appear weak and/or unreasonable.<sup>163</sup>

Finally, evaluating anticompetitive effects of litigation is also an important consideration in identifying suitable antitrust cases. In the Hatch-Waxman context, filing and maintaining baseless litigation is likely to impede competition in cases where it delays generic entry. In other contexts, it may be far more difficult to demonstrate that sham litigation, either by itself or along with other conduct, is anticompetitive.

Applying these criteria will assist in identifying appropriate cases for potential antitrust liability. And while the criteria discussed focuses

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161. *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 2012 WL 95592, at \*1 (D. Del. Jan. 12, 2012). *Accord AstraZeneca*, 2010 WL 1375176, at \*4 ("Astra never put forth any evidence of infringement and any reasonable party would have known that this action should have been terminated early.").

162. *AstraZeneca*, 2010 WL 1375176 at \*6 ("'[A]ll the discovery in the world' is what Astra wanted-and it wanted that discovery in order to keep defendants' product off the market for as long as possible.' One of the ways in which Astra needlessly prolonged this litigation, and increased the cost of defending it, was to insist on wide-ranging discovery—even going so far as to tell the court that Hatch-Waxman litigation was supposed to require lots of discovery. A determination that Astra maintained this action in bad faith is supported by my findings that, 'Astra was a party in search of a theory on which to proceed,' that Astra 'obviously wanted unlimited discovery,' and that Astra's discovery requests 'smack of a fishing expedition.'") (citations and ellipsis omitted). *Accord Eon-Net LP v. Flagstar Bancorp.*, 653 F.3d 1314, 1325 (Fed. Cir. 2011) (various litigation conduct found, including not engaging in claim construction process in "good faith," evasive conduct, and an overall "lack of regard for the judicial system" as evidenced by depositions and interrogatory responses.).

163. *Beckman Instruments v. LKB Produkter AB*, 892 F.2d 1547, 1552 (Fed. Cir. 1989) ("[T]he district court's finding of exceptional circumstances is based on a *strategy* of vexatious activity."); *Eon-Net*, 653 F.3d at 1324, 1327 (patentee's "numerous instances of litigation misconduct," which included filing dozens of baseless suits "to extract a nuisance value settlement" all supported an award of fees under Section 285). *Cf. Cal. Motor Transp. v. Trucking Unlimited*, 404 U.S. 508, 513 (1972) ("[A] pattern of baseless, repetitive claims may emerge which leads the fact finder to conclude that the administrative and judicial processes have been abused"); *Primetime 24 Joint Venture v. Nat'l Broad. Co.*, 219 F.3d 92, 101 (2d Cir. 2000); *USS-POSCO Indus. v. Contra Costa County Bldg. & Constr. Trades Council*, 31 F.3d 800, 810–11 (9th Cir. 1994).

on patent litigation in the Hatch-Waxman context, several may be applied in other contexts. For example, a lack of due diligence in evaluating the strength of one's claim prior to filing suit may be indicative of improper motive in nearly any action. Similarly, continuing to take an unreasonable and unsupportable position throughout litigation concerning the language of a relevant document (such as a contract)—particularly if inconsistent or even contradicted by other evidence—is likely to suggest an improper motive for the litigation. Finally, misconduct during the course of litigation surely happens in all types of cases, and in certain situations may evidence that the litigation is being maintained for an improper purpose.

#### CONCLUSION

Maintaining objectively baseless litigation may violate the antitrust laws. While it is beyond dispute that *filing* objectively baseless litigation may be the basis for antitrust liability, there is little case law on whether and when *maintaining* baseless litigation may be so as well.

Antitrust concerns with maintaining baseless litigation extend far beyond the pharmaceutical context. Rather, the focus on pharmaceutical cases is primarily due to the author's familiarity with the field, the importance of pharmaceuticals as a national issue, and the common (though not universal) view that there is substantial anticompetitive conduct occurring in the pharmaceutical industry. Additionally, due to certain unique features of its regulatory context, demonstrating anticompetitive effects of maintaining baseless litigation is likely to be easier in pharmaceutical litigation than in other contexts.

Antitrust claims for maintaining baseless litigation are not likely to become common—even in pharmaceutical cases. The difficulty of meeting various, formidable substantive and procedural requirements for antitrust liability will likely limit the viability of pleading and proving such claims. Nevertheless, even if not-often used, it could be a “big stick” to assist in combating anticompetitive conduct and deterring frivolous litigation.